



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,212	04/05/2001	Ying-Fci Wei	1488.1280006	3523
28730	7590	01/28/2005	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			O HARA, EILEEN B	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 01/28/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,212

Applicant(s)

WEI ET AL.

Examiner

Eileen O'Hara

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 283-305 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 283 and 285-305 is/are rejected.
- 7) ☒ Claim(s) 284 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Nov. 15, 2004 has been entered.

Claims Status

2. Claims 283-305 are pending in the instant application. Claims 221-282 have been canceled and claims 283-305 have been added as requested by Applicant in the Paper filed Nov. 15, 2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 283 and 285-305 are rejected under 35 U.S.C. 102(e) as being anticipated by Ashkenazi et al., US Patent Application Publication No.2002/0161202, effective filing date June

Art Unit: 1646

18, 1997 (08/878,168), for reasons of record in the previous Office Actions mailed October 20, 2003, and June 14, 2004, and below.

Claims 283 and 285-305 encompass isolated polypeptide of the extracellular domain or fragment of the extracellular domain of SEQ ID NO: 2 or polypeptide 90% or 95% identical to the extracellular domain (encoded by the cDNA clone contained in ATCC Deposit No. 97788), produced by a eukaryotic host cell, further comprising a heterologous polypeptide which may be a human immunoglobulin Fc region, and composition comprising the polypeptide and a carrier, and are thus drawn to the same invention as original canceled claims 117-220 and canceled claims 283-305.

On pages 6-10 of the response, Applicants traverse the priority determination, and assert that the Examiner's focus is misplaced, because the claims are not directed to "a TNF type receptor", but rather to the extracellular domain of SEQ ID NO: 2, for which Applicants have clearly asserted a substantial, specific and credible utility as discussed herein. Applicants cite the Revised Interim Utility Guidelines Training Materials at page nine and Example 8 at pages 45 and 46, and assert that the first priority document discloses that soluble forms of TNFR inhibit apoptosis, which is a well-known biological function, and that Example 5 of the present application demonstrates this utility.

Applicants' arguments have been fully considered and are persuasive that provisional application 60/035,496 disclosed a specific and substantial utility for the soluble receptor. However, provisional application 60/035,496 does not provide an enabling disclosure of how to use the soluble receptor. Apoptosis can be caused by many ligands in the TNF family, and the soluble receptor of the instant invention does not inhibit apoptosis caused by any ligand, but only

Art Unit: 1646

apoptosis mediated by TRAIL. Although provisional application 60/035,496 disclosed a number of diseases or conditions in which inhibition of apoptosis would be desirable, those diseases or conditions are mediated by different ligands, and the application did not provide support for which disease or condition could be treated with the soluble receptor. Therefore the effective priority date remains August 7, 1997, and the claims are rejected.

Claim 284 is not included in the rejection, since claim 284 claims the polypeptide *consisting of* amino acids 1 to 214 of SEQ ID NO: 2, and Ashkenazi et al. teaches that the extracellular domain of the protein is either amino acids 1 to 236 or 1 to 161 of the protein of SEQ ID NO: 1 (corresponding to amino acids -26 to 210 and -26 to 135 of the protein of SEQ ID NO: 2 of the instant invention), while the instant application teaches that the extracellular domain is amino acids -26 or 1 to amino acid 214, and also teaches that a fragment of the protein, amino acids 27 to 123 of SEQ ID NO: 2, retains apoptosis inhibiting activity.

It is believed that all pertinent arguments have been answered.

Conclusion

4.1 Claim 284 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4.2 Claims 283 and 285-305 are rejected.

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (571) 272-0829.

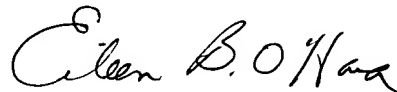
The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner



EILEEN B. O'HARA
PATENT EXAMINER